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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/680,313

10/06/2003

Usha Kasid

GTU-06-1183WO-US

5935

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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

05/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/680,313	Applicant(s) KASID ET AL.	
	Examiner Amy H. Bowman	Art Unit 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 12-15 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11 and 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                        |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/9/04, 5/31/05</u> | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Applicant's election without traverse of group I, claims 1-7, 9, 11 and 16-18, in the reply filed on 3/8/07 is acknowledged.

Claims 8, 10, 12-25, and 19-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/8/07.

### ***Claim Objections***

Claims 9 and 11 are objected to because they depend on claims 8 and 10, respectively, which are claims that have been withdrawn as being drawn to nonelected inventions.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 are directed to the epitope-bearing portion of claim 16 which comprises amino acids. However, the epitope-bearing portion of claim 16 is a portion of a polynucleotide, which would not comprise amino acids, but would rather comprise

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nucleotides. Therefore, claims 17 and 18 are inoperable as instantly claimed and have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 7 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al. (US 2001/0053519 A1).

The invention of the instant claims is directed to an isolated nucleic acid with the structural characteristics recited in instant claim 1, wherein the isolated nucleic acid molecule is DNA, as well as an epitope-bearing portion of the polynucleotide encoded by a nucleic acid sequence comprising SEQ ID NO: 1. It is noted that there is no definition in the instant specification for “epitope-bearing portion” and it is not a term of the art. In absence of such guidance to show which portions of a polynucleotide are “epitope-bearing”, any portion of the polynucleotide is considered to meet the instant limitation of “epitope-bearing” for purposes of the instant examination.

Fodor et al. teach hybridization of DNA to an array containing all possible 10-mer oligonucleotides. Therefore, Fodor et al. teach a 10-mer DNA polynucleotide that is 100% identical to SEQ ID NO: 1 or the complement of SEQ ID NO: 1, as required by part (d) of instant claim 1. The polynucleotide comprises ten contiguous nucleotides from the nucleic acid sequence contained in SEQ ID NO: 1. As explained above, the polynucleotide is considered to meet the instant limitation of having an "epitope-bearing" portion. Therefore, the instant claims are anticipated by Fodor et al.

Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US 6,008,434).

The instant claims are directed to a recombinant vector and host cell produced by the methods of claims 8 and 10, respectively.

Lee et al. teach a recombinant vector and host cell. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (see MPEP 2113).

Therefore, the instant claims are anticipated by Lee et al.

Claims 1-7, 9, 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (US 6,569,662 B1).

The invention of the instant claims is directed to an isolated nucleic acid with the structural characteristics recited in instant claim 1, wherein the isolated nucleic acid molecule is DNA, as well as an epitope-bearing portion of the polynucleotide encoded by a nucleic acid sequence comprising SEQ ID NO: 1. It is noted that there is no definition in the instant specification for "epitope-bearing portion" and it is not a term of the art. In absence of such guidance to show which portions of a polynucleotide are "epitope-bearing", any portion of the polynucleotide is considered to meet the instant limitation of "epitope-bearing" for purposes of the instant examination.

Tang et al. teach a 2783 nucleotide polynucleotide sequence that comprises nucleotides 1-305 of instant SEQ ID NO: 1, meeting the instant limitation of a polynucleotide comprising nucleotides 1 to "about" 456 of SEQ ID NO: 1 (see SEQ ID NO: 107 of Tang et al. and result 1 on sequence search results in SCORE labeled as "20070328\_133051\_us-10-680-313-1.rni").

The sequence of Tang et al. comprises 305 contiguous nucleotides of instant SEQ ID NO: 1 and is a DNA sequence. As explained above, the polynucleotide is considered to meet the instant limitation of having an "epitope-bearing" portion.

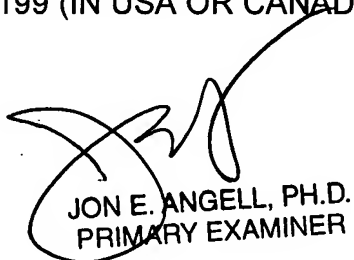
Tang et al. teach recombinant vectors and host cells transformed with the vectors made by inserting the polynucleotide sequences of Tang et al. into the expression vector in operable linkage to a promoter and introducing the vectors into a host cell. Therefore, the instant claims are anticipated by Tang et al.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JON E. ANGELL, PH.D.  
PRIMARY EXAMINER

Amy H Bowman  
Examiner  
Art Unit 1635

AHB